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Ethylene Oxide Commercial Sterilization Section 114 Survey Response
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division,
Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

Re: Ethylene Oxide Commercial Sterilization Section 114 Survey Response by Medtronic

Dear Sir or Madam:

Please find enclosed Medtronic's response to the Environmental Protection Agency's ("EPA") Ethylene Oxide Commercial Sterilization Section 114 Survey, dated December 9, 2019. The Section 114 Survey identified the following facilities:

- Covidien, 195 McDermott Road, North Haven, CT
- Medtronic Puerto Rico, State Road 149 Km 56.3, Villalba, PR
- HeartWare, 14440 Northwest 60th Avenue, Miami Lakes, FL
- Xomed Surgical Products, 6743 Southpoint Drive North, Jacksonville, FL
- Medtronic – Rice Creek, 7000 Central Avenue Northeast, Fridley, MN
- Medtronic PRL, 11520 Yellow Pine Street Northwest, Coon Rapids, MN

Medtronic has also prepared a response for the following facility that was not identified in the Section 114 Survey:

- MPROC – Juncos, Road 31, KM 24.4, Ceiba Norte Industrial Park, Juncos, PR

As requested by the EPA and in accordance with Section 114 of the Clean Air Act, 42 U.S.C. § 7414, Medtronic has made all reasonable efforts within the time provided by the Agency to collect and organize the information and records requested by the Section 114 Survey. EPA has also instructed that the Section 114 Survey only requests readily available information on emissions from ethylene oxide sterilization operations at the facility level, so Medtronic did not create any new documents to respond to the Section 114 Survey.[1]

[1] *See* EPA letter to Medtronic counsel, dated January 10, 2020, clarifying that the Section 114 Request is "designed to only collect readily available information on emissions from ethylene oxide sterilization operations at the facility level."

Medtronic has collected and organized all readily available information in the enclosed Microsoft Excel survey form and accompanying Attachments. Accordingly, Medtronic hereby submits the enclosed response to the Section 114 Survey in accordance with its obligations under the Clean Air Act. If additional information that is responsive to the Section 114 Survey becomes readily available, Medtronic reserves its right to supplement its responses as appropriate. Please note the Medtronic Heartware facility does not currently operate an ethylene oxide sterilizer, so we have not included information regarding that facility except for general site information requested in the Section 114 Survey.

Confidential Business Information

In accordance with 5 U.S.C. § 552(b)(4), 40 CFR Part 2, Subpart B, and other applicable authority, Medtronic has submitted a separate response to the Section 114 Survey that includes confidential business information ("CBI"). Based on the instructions provided by EPA, CBI has not been provided with the enclosed non-CBI response to the Section 114 Survey, and the enclosed Microsoft Excel survey form includes blank, red cells to denote CBI where applicable.

If any information designated as CBI has been inadvertently provided with the enclosed non-CBI response to the Section 114 Survey, or if EPA intends to consider making publicly available any information that Medtronic has designated as CBI, Medtronic respectfully requests the opportunity to address EPA's questions or concerns prior to any final agency confidentiality determination or public disclosure.

Certification

In the Section 114 Survey, EPA has requested that separate certifications should be provided by four individuals, a reporter, facility representative, professional engineer, and certified industrial hygienist. EPA has not provided an explanation or basis as to why it has requested separate certifications for a single response to the Section 114 Survey. EPA also has not explained why the individuals listed by the Agency are needed to certify the specific information or records requested by the Section 114 Survey.

Accordingly, Medtronic objects to providing four separate certifications for its response to the Section 114 Survey. Doing so would be burdensome and unnecessary, would be likely to cause unnecessary confusion, and exceeds the Agency's authority to collect reasonable records and information under Section 114 of the Clean Air Act. Medtronic has designated the following representative to certify its responses to the Section 114 Survey:

Peter Joseph Jansen, PE
Medtronic
Senior Director of Environmental Health and Safety – Americas

Based on review of Medtronic's response to the Section 114 Survey, readily available records and information, and discussions with facility personnel, Mr. Jansen has certified to the best of his knowledge and belief that the statements and information included in Medtronic's response to the Section 114 Survey are true, accurate, and complete. Further, as requested by EPA, Medtronic has identified Mr. Jansen as the person who is available for follow-up questions, if any, from EPA regarding the information provided in the Survey.

Please contact John Griffith at john.griffith@us.dlapiper.com or 410.580.4166 or me at paul.wierenga@us.dlapiper.com or 202.799.4401 if you have any questions regarding the enclosed response to EPA's Section 114 Survey.

Best regards,

Paul Wierenga
John E. Griffith, Jr.

PW:

cc: Patricia Duft, Medtronic
Peter Jansen, Medtronic
Valora Putnam, Medtronic
Anita Tuch, Medtronic